IT Capabilities For The Realization of The Laboratory Without Walls

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This article presents the factors that are driving the restructuring of laboratory services and the information technology capabilities that are necessary to support the regionalized laboratory services organization. The overall need is for a trans-entity laboratory information system with point of care ordering and results reporting and enterprise-wide specimen transportation and tracking, that is interfaced with other information resources required for clinical decision-making, and patient care, operational, and financial management.

INTRODUCTION: UNDERSTANDING THE BUSINESS ISSUES

It is commonplace in the United States and increasingly frequent in Canada, that healthcare organizations are considering and forming regional entities (integrated delivery systems) to deliver healthcare services[1]. Healthcare reform, decreasing public funding, the advent of managed care, and the recognition of the value of an integrated healthcare system motivate the formation of institutional networks, and the consolidation of locally-suboptimal services.

One area of particularly intense regionalization activity is that of developing shared or at least regionally coordinated and rationalized laboratory services. The rethinking of laboratory services on a trans-institutional basis is driven by many factors, among which the following are particularly important:

- In the United States it was recognized that the DRG-based funding turned the laboratory from a profit center (as it was under fee-for-service) to a cost center, and that controlling the cost of these services was essential to maintaining institutional profitability.

- Managed care has intensified the interest in reducing unnecessary utilization and optimizing laboratory performance to cost ratio.

- In Canada, the combination of the shrinking healthcare budget, and pressure or directives from government to organize and optimize the healthcare system on a regional basis, have provided the motive force towards the realization of economies of scale.

- In both countries, the new laboratory diagnostic technologies that have become available, the recognition of the need for fully integrated clinical information to enable competent diagnosis and patient management, and the recognition of the clinico-strategic value of the accessible longitudinal patient record have dictated innovative thinking. Not only have the rules of the game been changed, but new cards have been put in the deck, including point-of-care (POC) testing devices, near-patient satellite testing facilities, new testing technologies, highly capable and high-volume instrumentation, and robotics, all with wireless connectivity.

The rethinking of the laboratory services component healthcare system is leading to real re-engineering: not local streamlining, but genuine innovation and radical restructuring of laboratory services. This rethinking has "front-burnered" interventions such as the establishment of regional roboticized laboratories, the implementation of highly automated local core labs, the development of regional centers of excellence for esoteric testing, the move to alternate site testing (including point of care and near patient testing), the formation of regional laboratory services administrative entities, the implementation of sophisticated, efficient, specimen acquisition and transportation systems, and dramatic re-organization, cross-training, and optimization of the roles and deployment of laboratory professionals.

The Laboratory Without Walls will have the following major characteristics:

- testing will be performed at a location that ensures the optimization of the value of lab testing for the care of the patient. POC testing will play a significant role as turn-around time (TAT) can be

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minimized. The high variable costs of POC devices will be offset by their low fixed costs and by the value of the immediate results. POC results will be captured via wireless connections.

- satellite near-patient testing facilities will exist now that the quality control, operation, and connectivity issues associated with these facilities have been addressed. The need for rapid TATs drives their existence. Satellite facilities will be fully-integrated via the enterprise IT system.

- the classic laboratory will down-size and become highly automated, with specific labs in the region becoming responsible for esoteric tests, with specimens transported to them via a tightly-monitored, IT-assisted specimen transportation system.

- tests with longer TATs will be processed at on-site or off-site regional and possibly national robotic laboratory testing centers, with full connectivity with the above, and with appropriate extensions of the specimen transportation system. Economies of scale will be the drive here.

Laboratory testing will no longer be localized, but will be distributed to optimize total patient care cost, and then the cost of testing. Furthermore, there will be continuous reconfiguration of the location of testing as technology and other factors change.

THE ROLE OF IT

The innovators of laboratory services have recognized the mission-critical importance of information technology to the implementation of the rethought laboratory services organization. Not so long ago, the Community Health Information Network (CHIN) was a technology looking for a business rationale, and many CHINs have had hard times lacking this rationale. For the laboratory services rethinkers, the CHIN is the essential utility to enable the re-engineered service.

Beyond the obvious need for an inter-entity information transport mechanism, though, the true and full nature of the IT requirements has at best been perceived "through a glass, darkly".

Here, we look beyond the basics: the need for an inter-entity CHIN and for capable local or shared Laboratory Information Systems (LISs). We also ignore the supportive services (such as the enterprise-level IS department and the enterprise CIO) that are essential to implement and maintain the panoply of technologies, the organizational structures necessary to deploy these services, and the re-engineering of work processes required to maximize the value of the technologies. The focus of this article is on understanding what is required of the systems that will utilize the CHIN to operationally integrate disparate information systems to provide the infrastructure for re-engineered laboratory services.

UNDERSTANDING THE IT REQUIREMENTS OF THE LABORATORY WITHOUT WALLS

The most abstract statement of the IT requirement is that we must create a trans-entity laboratory information system with point of care ordering and results reporting that is integrated with other information resources required for clinical decision-making, and patient care, operational, and financial management.

The major characteristics of an IT solution that addresses this requirement are:

1. **The solution must address the multiple, heterogenous "legacy" LIS environment.**

   The typical regional situation involves in the range of 5 to 15 or more participating entities (e.g., hospitals and clinics that provide laboratory services), and one or more commercial laboratory providers, each having a different LIS or substantially different implementations of a specific LIS.

   Although the selection of a single LIS with multi-site capabilities would be a strong technical/economic preference, this will generally only be a consideration in tight consolidation ventures, wherein laboratory services (and other or all components of the healthcare delivery system) are merged or under common governance, and/or in those situations when all LISs are near the end of their life-cycle.

   Even clients with the same vendor may have substantially different implementations of their LISs. Specific LISs allow a very high degree of customization, and individual implementations of these need to be considered as virtually different products.

   One implication of this is high interfacing costs, when, as often is the case, each interface is

treated by the vendor as a separate development. This interfacing cost dominates the cost side of the business case.

Even clients with products that restrict customization will generally be implemented with significantly variant data definitions, test menus, procedures, normals, etc., requiring a significant investment in the development of data standards.

To minimize interfacing and support costs, all LISs of the same vendor must be brought up to the same version, and required missing modules must be acquired. Note that this upgrading may require a significant investment in hardware (e.g., replacing Vaxes with Alphas). This upgrading cost is the second most important component of the IT cost equation.

2. **Often, each participating entity will have different vendors' products addressing their other IT needs: e.g., differing HISs, OE/RR packages (Order Entry, Results Reporting; these may be separate packages), ADT, and Billing/Finance systems. Best-of-breed strategy sites will have several different vendors' products .**

   This implies the development of many interfaces, as the full solution may require interfaces to the LIS, OE, RR, ADT, and Billing systems.

   The importance of the enterprise-wide connectivity to OE and RR interfaces is yet another argument for the adoption of a single enterprise-wide OE/RR system that also provides a consistent user interface invariant of locus of care.

3. **Few, if any, participants will be willing to replace their existing systems.**

   Although wherever possible (particularly in those situations where a merged entity is the resultant configuration, and for reasons of economics and simplicity) the minimization of the number of different LISs should be encouraged (primarily to reduce the technical and support team complexity, and support costs), in most instances this is not acceptable to the participants.

   Labs with outdated and/or limited functionality LISs, with significant maintenance problems and/or problematic support, and/or where significant re-implementation is required, are particularly good candidates for conversion to a "common" LIS.

4. **Many regional entities/networks will adopt a "mosaic" lab services architecture (tests are performed at "centers of excellence"), and/or provide a high-volume central service. Consequently, tests may be processed at any participating lab, and/or near or at the point of care, and/or at a central facility.**

   There are many possible "rules" for the choice of processing site: specific tests may always be performed at a selected site, some tests may be processed at the originating institution's (the institution/entity from which the order originated, i.e., the hospital ward or the ambulatory care center office) lab during certain times/situations (e.g., specific times of day, or when equipment is serviceable, or during vacation periods, etc.) and at another site during other times/situations. Often, an order may be split to be processed at several sites (time/situation variant). There must be excellent systems support for rules specification and maintenance.

   An implication of this is that an excellent specimen identification, shipping, and tracking system, employing computer-readable (e.g., bar code) labeling, interfaced to the LISs, must be part of the solution.

   Another implication is that near-patient device connectivity is crucial.

5. **Test requisitions and results (and specimens) are required to flow among institutions in a reliable and transparent manner.**

   Orders created with the originating institution's OE system, must be registered at the originating institution's LIS, and passed to one or more processing institutions' LISs.

   Results and status information must flow in the reverse pathway, from the processing institution's LIS, being registered at the originating institution's LIS, and passed to the originating institution's RR system.

   Specimens originating at any site, must be acquired, identified and registered, split, and shipped, moving to any processing site, while being tracked throughout.

The advent of the clinical data repository and the data warehouse require their integration. This is particularly important as results reporting will likely be provided via the clinical data repository.

6. **Each participating institution and the enterprise as a whole must be able to track and report its "processed here" and "pass through" workloads.**

   Even if a central repository is created for results, the individual LISs' management/operational databases must be updated to support management reporting. It is possible that the use of a central repository and the existence of adequate management reporting software based on this repository, will eventually allow the relaxation of the requirement that orders and results reports be registered at the individual LISs.

   In looser regionalization ventures, a repository may not be a viable solution, as strict ownership, control and confidentiality of information will be a requirement.

7. **A "seamless" and "transparent" information system is required to enable this.**

   No ordering provider at any participating entity can be affected by the restructuring of lab services, other than by the potentially slower turnaround of tests processed remotely.

   The IS environments of the participating institutions/entities will not, unless desired, be affected by the lab restructuring, other than the interfacing of specific packages to a "meta-Interface Engine" (an interface engine that operates at the enterprise/regional level).

   Data standardization is essential, including ultimately: common test definitions and menus, common testing standards/normals, common procedures manual, etc.

8. **The IT solution for labs must be extendable to other services suited to regionalization (e.g., Diagnostic Imaging, Nutrition, Pharmacy, Specialist Consults, Materials, etc.)**

   The solution cannot be unique to labs, requiring replacement/reworking to serve the needs of other ancillary services rationalization.

   At least part of the cost of the solution must be attributable as infrastructure for other such ventures.

9. **All origins for orders and destinations for results must be able to be included under the same overall solution.**

   Orders must be able to originate at and be returned to any point of care or work, whether in the hospital, ambulatory care clinic, provider's office, etc.

   Although, optimally, ordering would be via an enterprise-wide OE/RR capability, the practical situation is the existence of many OE/RR systems (i.e., differing interfaces in the provider's office, in the ambulatory clinic, and in the hospital).

10. **Preferably, the solution will not "take sides" with any of the existing LIS/HIS vendors, but will be perceived as an "open" and "generic" solution.**

    The selection of an LIS vendor's integration solution has been and may be a negative in a situation where that vendor's LIS is not favored by some or all of the participants.

11. **The solution must fit well with the participants' IT strategies.**

    The solution must append to or be an extension of existing IT strategic plans, not require their realignment, must be an affordable component of the cost of regionalization, and must be supportable by an "economical" enterprise-level IT service organization, if such is desired.

12. **The solution must not require the adoption of a unique patient identifier by all participants.**

    Although, ideally, in the case of consolidations, all participants should adopt a common unique patient identifier for record linkage purposes, the massive change to accomplish this must not be a barrier to regionalization. In the case of networks of competing labs, this solution awaits higher-level resolution. Therefore, the solution must preserve the association of the originating institution's patient/specimen identifier with the order/specimen, and must support the mapping of institutional identifiers to an enterprise unique

identifier to enable the maintenance of a regional longitudinal patient record.

13. **The solution must address the issue of vulnerability, i.e., being the single point of failure for lab services.**

    High performance, reliable, redundant, and fail-soft systems and communications links, data protection and integrity preservation, and disaster recovery are essential components of the solution.

14. **Security must be adequate to address participants' standards and requirements.**

15. **The realization of the full solution will, by the very nature of its complexity and magnitude, requires a comprehensive, locally-customized array of laboratory-related and IT advisory services, information and communications technologies and network (local and wide area) services, implementation and maintenance services, with a set of financing options (including price by usage).**

    It will be very rare that all of the expertise and resources requirements can be addressed from within the participating institutions.

THE TYPES OF SOLUTIONS

The purpose of this article is the full comprehension of the problem. However, the types of possible solutions are predictable, even though, at the time of writing, none is available "off the shelf":

- **Homogenize/Integrate**

  All hospitals abandon their separate LISs and invest in a single, shared, multi-institutional product. This may have distributed hardware with truly integrated software, including an integrated database, or it may have a central system with links into the individual labs.

- **Stay Heterogenous/Interface**

  The material above describes the characteristics of this solution. The technology required is essentially that delivered by the interface engine companies, augmented by "intelligent" routing (rule based information flow to and from sources and destinations), enterprise patient index with record identifier synonym support, a specimen shipping and management package, and several other capabilities to address non-HL-7 interfacing). It is also possible that e-mail-enabled workflow automation systems can be the information transport mechanism, and the use of a "dummy" LIS as an information-routing tool is also possible.

The clear implication of this article is that the latter will be the prevalent solution as the dream of regionalization of laboratory services becomes reality.

Our experience base is currently in excess of 50 such ventures, many with more than 10 participating entities. We have found that the IT requirements stated above are consistent and mission critical. Our review of interface engine vendors, LIS vendors, CHIN-providers, and integrators has uncovered only partial solutions. The primary gaps relate to the problems of "intelligent routing", and the complexity, cost, and time requirements associated with interfacing to existing systems. Unfortunately, the lack of a comprehensive solution has not impacted the sales efforts of some "solution providers", and disappointment is not an uncommon deliverable.

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Reference

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